II. REMARKS

Claims 85-97 are pending. Claims 1-3, 6-8, and 82-84 have been withdrawn. Claims 4, 5, and 9-81 have been cancelled. Claim 85 has been amended.

A. 35 U.S.C. § 112, second paragraph

In the Office Action, the Examiner rejected claims 85-88 under 35 U.S.C. § 112, second paragraph, asserting that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner specifically referred to the amount of inert diluent recited in claims 85 and 87 ("0-89%), asserting that it is unclear if the inert diluent is a required component.

Applicants respectfully submit that one of skill in the art would understand that the formulation of claims 85 and 87 do not require the presence of a diluent, but when the diluent is present, then it is present in the range of from about 0 to about 89 percent. Support for the inert diluent being present in a range of from about 0 to about 89 percent, is found in the specification at page 4, lines 25-31, which reads "[t]he present invention is also related to a method for providing a sustained release formulation of a medicament having poor solubility in water, comprising preparing a sustained release excipient comprising from about 10 to about 99% by weight of a gelling agent, from about 1 to about 20% by weight of a cationic cross-linking agent, and from about 0 to about 89% by weight of an inert pharmaceutical diluent . . ." Additional support in the specification is found at page 10, lines 14-19, which reads, "[i]n certain embodiments of the present invention, the sustained release excipient comprises from about 10 to about 99 percent by weight of a gelling agent comprising a heteropolysaccharide gum and a homopolysaccharide gum, from about 1 to about 20 percent by weight of a cationic crosslinking agent, and from about 0 to about 89 percent by weight of an inert pharmaceutical diluent." Further support for the claimed range is found in original claims 22 and 40 as filed, which are

part of the specification. Therefore, claims 85 and 88 meet the requirement of 35 U.S.C. § 112, second paragraph. As claim 86 depend from an incorporates the limitations of claim 85, it too meets such requirements.

In view of the above, it is respectfully requested that the rejection be withdrawn.

B. 35 U.S.C. § 102(b)- U.S. Patent No. 4,693,728 to Clare et al.

In the Office Action, the Examiner rejected claims 85 and 86 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,693,728 to Clare et al. (hereafter "the Clare patent").

Claim 85 as amended recites, in pertinent part, "[a] method of preparing a sustained release excipient for pharmaceutical use. . ." In contrast, the Clare patent does not teach a method of preparing a sustained release excipient for pharmaceutical use. The Clare patent is purportedly directed to hydrocolloid/salt blends especially useful in alginate print paste compositions. (Clare patent abstract). Although the Clare patent does discuss various food-related uses of its hydrocolloid/salt blends, (e.g., "gelled foods such as pet foods, sauces, gravies, bakery fillings . . ." it does not disclose a sustained release excipient for pharmaceutical use as claimed in the present invention. Therefore, the Clare patent cannot anticipate claim 85 of the present invention. As claim 86 depends from and incorporated the limitations of claim 85, it also cannot be anticipated by the Clare patent.

Applicants respectfully request that the rejection be withdrawn.

C. 35 U.S.C. § 102(b)- U.S. Patent No. 3,456,049 to Hotko et al.

In the Office Action, the Examiner rejected claims 85, 87 and 88 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,456,049 to Hotko et al. (hereafter "the Hotko patent").

In response, Applicants respectfully submit that the Hotko patent is purportedly directed to an excipient which comprises a fatty substance, alginic acid, and a granulating liquid. The Hotko patents fails to teach "a pharmaceutically acceptable cationic crosslinking agent capable of cross-linking with said gelling agent when exposed to an environmental fluid to increase the gel strength" as recited in claims 85 and 87. The Hotko patent also fails to teach a pre-manufactured excipient to which a medicament is added, as evidenced by the Examples of the Hotko patent, which show all the ingredients, including medicament, mixed together. Therefore, claims 85 and 87 are not anticipated by the Hotko patent. As claim 86 depends from and incorporates the limitations of claim 85, and claim 88 depends from and incorporates the limitations of claim 87, they also are not anticipated by the Hotko patent.

Applicants respectfully request that the rejection be withdrawn.

D. 35 U.S.C. § 103(a)- U.S. Patent No. 4,994,276 to Baichwal et al. in view of U.S. Patent No. 4,795,642 to Cohen et al.

In the Office Action, the Examiner rejected claims 85-87, 89-93, 96 and 97 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 4,994,276 et al. (hereafter "the Baichwal patent") in view of U.S. Patent No. 4,795,642 to Cohen et al. (hereafter "the Cohen patent").

In his rejection of claims 85-87, 89-93, 96 and 97, the Examiner acknowledged that the Baichwal patent does not specify a cationic cross-linking agent and therefore resorted to the Cohen patent which purportedly teaches the use of a cationic gelling agent. The Examiner presumes that one of skill in the art would have been motivated to combine these references.

Applicant respectfully disagrees with the Examiner's presumption that these references are properly combinable. The Baichwal patent is directed to a sustained release excipient which includes a heteropolysaccharide and a polysaccharide material capable of cross-linking the heteropolysaccharide. As acknowledged by the Examiner, the Baichwal patent does not teach or

suggest a cationic cross-linking agent, as claimed in the present invention. The Baichwal patent also teaches a pre-manufactured excipient to which a medicament is added. Further, the only dosage form described in the Baichwal patent is a granulation which can be compressed with a medicament into tablets.

In contrast, the Cohen patent purportedly describes a gelatin capsule enclosing a solid matrix formed by the cation-assisted gellation of a liquid fill. More specifically, the Cohen patent purportedly teaches the addition of a cationic gelling agent to a liquid fill, with the liquid fill purportedly gelling when it comes into contact with the cationic gelling agent to form a solid matrix. There is no discussion in the Cohen patent of a medicament added to a pre-manufactured excipient. Further, in the Cohen patent the medicament is actually part of the liquid fill to which the cationic cross-lining agent is added. This is very different from the pre-manufactured excipient of the Baichwal patent.

The Cohen patent is not properly combinable with the Baichwal patent as there would be no motivation for one of skill in the art to combine these references. It is only through use of impermissible hindsight that the Examiner is able to combine the cited references to obtain the present invention. The Examiner has cherry picked from the Cohen patent and inserted that cherry into the Baichwal patent, a patent whose teaching is clearly incompatible with that of a liquid fill gel capsule of the Cohen patent.

As stated in *In re Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002):

> "The factual inquiry whether to combine references must be thorough and searching." *Id.* It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. *See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124-25, 56 U.S.P.Q.2d 1456, 1459 (Fed. Cir. 2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential component of an obviousness holding' ") (quoting *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352,

48 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."); *In re Dance*, 160 F.3d 1339, 1343, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); *In re Fine*, 837 F.2d 1071, 1075 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) ("'teachings of references can be combined *only* if there is some suggestion or incentive to do so.'") (emphasis in original) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984).

Pursuant to the test of *In re Lee*, there is no teaching, motivation, or suggestion to select and combine the cited references relied on as evidence of obviousness in the present application.

Therefore, claims 85, 87, 89, 91, 92, 93, 96 and 97 cannot be rendered obvious over the combination of these references. As claims 86 depends from and incorporates the limitations of claim 85, it also is not obvious. As claim 90 depends from and incorporates the limitations of claim 89, it also is not obvious.

In further regard to claim 87, the Baichwal patent does not disclose or suggest a hydrophobic agent. As also acknowledged by the Examiner, the Cohen patent does not disclose or suggest a hydrophobic agent and therefore cannot cure the deficiency of claim 87. Thus, claim 87 is not rendered obvious by the combination of the Baichwal patent and Cohen patent.

Therefore, the Examiner is respectfully requested to withdraw this rejection.

E. 35 U.S.C. § 103(a)- U.S. Patent No. 4,994,276 to Baichwal et al. in view of U.S. Patent No. 4,795,642 to Cohen et al. in further view of U.S. Patent No. 3,456,049 to Hotko et al.

In the Office Action, the Examiner rejected claims 85-88 under 35 U.S.C. § 103(a) as

being obvious over the Baichwal patent in view of the Cohen patent, in further view of the Hotko patent. The Examiner acknowledged that neither the Baichwal nor the Cohen patent teaches the use of a hydrophobic material and looked to the Hotko patent to cure this deficiency.

Applicants respectfully submit that claims 85 and 86 do not recite a hydrophobic material. For the reasons cited in the discussion above, claims 85 and 86 are not obvious in view of the Baichwal patent and Cohen patent. As the Examiner added the Hotko patent for the purpose of its hydrophobic agent, the addition of this reference cannot possibly render these claims obvious. They are additionally not rendered obvious for the reasons discussed below regarding claim 87.

With regard to claim 87, for the reasons provided above, claim 87 is not rendered obvious in view of the combination of the Baichwal patent and Cohen patent. Claim 87 is further rendered unobvious in view of the Baichwal, Cohen and Hotko patents for the reasons stated below.

As explained above, the Cohen patent is not properly combinable with the Baichwal patent. One of skill in the art would also have no motivation to combine the Hotko patent with the Baichwal patent.

The Baichwal patent actually mentions the Hotko patent in a discussion regarding the shortcomings of the prior art in which it states, "[t]he carrier bases which provide the slow release profiles in these disclosures can only be compressed into a tablet or a solid dosage form with the aid of other conventional tableting adjuvants such as binders and the like, and therefore contribute only to the slow release aspect of the final solid unit dosage form and not to the tableting aspects." (Baichwal patent at column 3, lines 8-14). Clearly, one ordinary skill in the art, upon reading the disclosure of the Baichwal patent would have absolutely no incentive to

look to the Hotko patent. Further, the Baichwal patent is directed to a pre-manufactured excipient to which a medicament is added. Although the Hotko patent describes an excipient, the examples all show a medicament mixed directly with excipient ingredients. The Hotko patent does not teach or suggest a pre-manufactured excipient.

Therefore, one of ordinary skill in the art would have no incentive to combine the teachings of the primary reference with the teachings of the Cohen and Hotko patents. Therefore, claims 85 and 87 cannot be rendered obvious over the combination of these references. As claim 86 depends from an incorporates the limitations of claim 85, it too is not obvious. As claim 88 depends from and incorporates the limitations of claim 87, it too is not obvious.

Applicants respectfully request that the rejection be withdrawn.

F. 35 U.S.C. § 103(a)- U.S. Patent No. 4,994,276 to Baichwal et al. in view of U.S. Patent No. 4,795,642 to Cohen et al. in further view of U.S. Patent No. 4,309,405 to Guley et al.

In the Office Action, the Examiner rejected claims 94 and 95 under 35 U.S.C. § 103(a) as being obvious over the Baichwal patent in view of the Cohen patent, in further view of Guley et al. (hereafter "the Guley patent"). The Examiner acknowledged that neither the Baichwal patent nor the Cohen patent teach an enteric coating and looked to the Guley patent to cure this deficiency.

As discussed above, the Baichwal patent is not properly combinable with the Cohen patent. Further, one of skill in the art would have no motivation to combine the teachings of the Baichwal or Cohen patents with the teachings of the Guley patent as explained below.

Again, the Baichwal patent teaches a pre-manufactured excipient to which a medicament is added. In contrast, the Guley patent is purportedly directed to a sustained release granulation composition including a seal coating, which exemplifies a medicament combined with the

excipient ingredients simultaneously, not added to a pre-manufactured excipient. Therefore, one of ordinary skill in the art would have no motivation to combine these references of contrary teachings.

Further, there is no indication in the primary reference that a seal coating is even needed. It is only through the use of impermissible hindsight that the Examiner would even think to combine these references.

As also explained above, the Cohen patent purportedly describes a gelatin capsule enclosing a solid matrix formed by the cation-assisted gellation of a liquid fill. More specifically, the Cohen patent purportedly teaches the addition of a cationic gelling agent to a liquid fill, with the liquid fill purportedly gelling when it comes into contact with the cationic gelling agent to form a solid matrix.

The Cohen patent is not properly combinable with the Guley patent. There would be no motivation for one of skill in the art to combine a liquid fill gel capsule of the Cohen patent with the granulation formulation of the Guley patent. Once again, it is only through use of impermissible hindsight that the Examiner is able to combine the cited references to obtain the present invention.

Further, even if the teachings of Baichwal, Cohen and Guley were combined, the result would likely be a formulation where all ingredients are mixed together, including the medicament, with a cationic cross-linking agent added after the medicament is added.

Therefore, independent claim 94 cannot be rendered obvious by the combined teachings of the Baichwal, Guley and Cohen patents. As claim 95 depends from claim 94, it also is not obvious.

Therefore, the Examiner is respectfully requested to withdraw this rejection.

G. Non-Statutory Obviousness-Type Double Patenting

The Examiner rejected claims 85-97 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,709,677; 6,245,356; 6,048,548; 5,512,297; 5,773,025 and U.S. Application No. 10/766688.With regard to this double patenting rejection, Applicants respectfully submit that the filing of terminal disclaimers will be considered upon notification that the pending claims are otherwise allowable. Accordingly, Applicants willingness to submit timely filed terminal disclaimers does not operate as an admission, acquiescence, or estoppel on the merits of an issue of obviousness *((See Ortho Pharmaceutical Corp. v. Smith, 959 F.2d 936, 22 U.S.P.Q.2d 1119 (Fed, Cir. 1992)).*

Conclusion

It is now believed that with the exception of the possibility of filing terminal disclaimers, the above-referenced rejections have been obviated and it is respectfully requested that the rejections be withdrawn.

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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